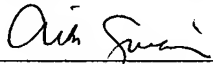




Patent Docket P1219P1C1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Timothy A. Stewart et al. Serial No.: 10/715,795 Filed: November 17, 2003 For: Fibroblast Growth Factor-19 (FGF-19) Nucleic Acids and Polypeptides and Methods of use for the Treatment of Obesity	Group Art Unit: 1646 Examiner: Unknown Confirmation No: 5748 CUSTOMER NO: 09157 CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on March 31, 2004  Aida Guian
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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

(x) **37 CFR §1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

0 **37 CFR §1.97(c)**

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of

allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.

☐ **37 CFR §1.97(d)**

- after the period specified in 37 CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

(If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.)

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. 09/522,342, filed March 9, 2000 and relied upon in this application for an earlier filing date under 35 USC §120.

☐ BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of

computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1 - A-0" (nucleotide) and "BLAST Results B-1 - B-0" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

- ☒ (x) not given
- ☐ given for each listed item
- ☐ given for only non-English language listed item(s) (Required)
- ☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

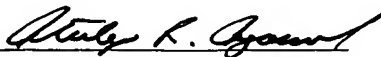
In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this sheet is enclosed.

Respectfully submitted,
GENENTECH, INC.

Date: March 31, 2004

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FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1219P1C1

Serial No.

10/715,795

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Goddard, A. et al.

Filing Date

17 Nov 2003

Group

1646

U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Name	Class	Subclass	Filing Date
* 1	4,378,347	29.03.83	Franco, W.			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Country	Class	Subclass	Translation Yes	No
* 2	HEI 12-511867		JAPAN				
* 3	WO 93/18186	16.09.93	PCT				

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

* 4	Abbass et al., "Altered expression of fibroblast growth factor receptors in human pituitary adenomas" <u>Journal of Clinical Endocrinology & Metabolism</u> 82(4):1160-1166 (Apr 1997)
* 5	Alitalo and Schwab, "Oncogene amplification in tumor cells" <u>Advances in Cancer Research</u> 47:235-281 (1986)
* 6	Altschul and Gish, "Local Alignment Statistics" <u>Methods in Enzymology</u> 266:460-480 (1996)
* 7	Arman et al., "Targeted disruption of fibroblast growth factor (FGF) receptor 2 suggests a role for FGF signaling in pregastrulation mammalian development" <u>Proc. Natl. Acad. Sci. USA</u> 95(9):5082-5087 (Apr 28, 1998)
* 8	Armstrong et al., "Expression of fibroblast growth factor receptors in human leukemia cells" <u>Cancer Research</u> 52(7):2004-2007 (Apr 1, 1992)
* 9	Aviezer et al., "Perlecan, basal lamina proteoglycan, promotes basic fibroblast growth factor-receptor binding, mitogenesis, and angiogenesis" <u>Cell</u> 79(6):1005-1013 (Dec 16, 1994)
*10	Baird and Bohlen, "Fibroblast Growth Factors" <u>Handbook of Exp. Pharmacol.</u> , Chapter 7, 95(1):369-418 (1990)
*11	Baselga et al., "HER2 Overexpression and Paclitaxel Sensitivity in Breast Cancer: Therapeutic Implications" <u>Oncology</u> (Supplement No. 2) 11(3):43-48 (March 1997)
*12	Baselga et al., "Phase II Study of Weekly Intravenous Recombinant Humanized Anti-p185HER2 Monoclonal Antibody in Patients With HER2/neu-Overexpressing Metastatic Breast Cancer" <u>J. Clin. Oncol.</u> 14(3):737-744 (Mar 1996)
*13	Bashkin et al., "Basic fibroblast growth factor binds to subendothelial extracellular matrix and is released by heparitinase and heparin-like molecules" <u>Biochemistry</u> 28(4):1737-1743 (Feb 21, 1989)
*14	Bishop, J., "Molecular themes in oncogenesis" <u>Cell</u> 64(2):235-248 (Jan 25, 1991)
*15	Bowie et al., "Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions" <u>Science</u> 247:1306-1310 (1990)
*16	Ciruna et al., "Chimeric analysis of fibroblast growth factor receptor-1 (Fgfr1) function: a role for FGFR1 in morphogenetic movement through the primitive streak" <u>Development</u> 124(14):2829-2841 (Jul 1997)
*17	Colvin et al., "Skeletal overgrowth and deafness in mice lacking fibroblast growth factor receptor 3" <u>Nature Genetics</u> 12(4):390-397 (Apr 1996)
*18	Dell and Williams, "A novel form of fibroblast growth factor receptor 2. Alternative splicing of the third immunoglobulin-like domain confers ligand binding specificity" <u>Journal of Biological Chemistry</u> 267(29):21225-21229 (Oct 15, 1992)

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P1219P1C1	Serial No. 10/715,795
LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)				Applicant Goddard, A. et al.	
				Filing Date 17 Nov 2003	Group 1646
OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)					
*19	Deng et al., "Fibroblast growth factor receptor 3 is a negative regulator of bone growth" <u>Cell</u> 84(6):911-921 (Mar 22, 1996)				
*20	Deng et al., "Murine FGFR-1 is required for early postimplantation growth and axial organization" <u>Genes & Development</u> 8(24):3045-3057 (Dec 15, 1994)				
*21	Evans et al., "cSRL-186H12-u cSRL flow sorted Chromosome 11 specific cosmid Homo sapiens genomic clone cSRL-186H12" (Accession No. B03767) (July 16, 1996)				
*22	Fiore et al., "Apparent normal phenotype of Fgf6-/- mice" <u>International Journal of Developmental Biology</u> 41(4):639-642 (Aug 1997)				
*23	Floss et al., "A role for FGF-6 in skeletal muscle regeneration" <u>Genes & Development</u> 11(16):2040-2051 (Aug 15, 1997)				
*24	Folkman et al., "A heparin-binding angiogenic protein--basic fibroblast growth factor--is stored within basement membrane" <u>American Journal of Pathology</u> 130(2):393-400 (Feb 1988)				
*25	Frontali et al., "Osteoporosis-pseudoglioma syndrome: report of three affected sibs and an overview" <u>American Journal of Medical Genetics</u> 22(1):35-47 (Sep 1985)				
*26	Goldfarb, M., "Functions of fibroblast growth factors in vertebrate development" <u>Cytokine & Growth Factor Reviews</u> 7(4):311-325 (Dec 1996)				
*27	Gong et al., "Osteoporosis-pseudoglioma syndrome, a disorder affecting skeletal strength and vision, is assigned to chromosome region 11q12-13" <u>American Journal of Human Genetics</u> 59(1):146-151 (Jul 1996)				
*28	Gospodarowicz et al., "Isolation of brain fibroblast growth factor by heparin-Sepharose affinity chromatography: identity with pituitary fibroblast growth factor" <u>Proc. Natl. Acad. Sci. USA</u> 81(22):6963-6967 (Nov 1984)				
*29	Gray et al., "Fluorescence in situ hybridization in cancer and radiation biology" <u>Radiation Research</u> 137(3):275-289 (Mar 1994)				
*30	Guo et al., "Keratinocyte growth factor is required for hair development but not for wound healing" <u>Genes & Development</u> 10(2):165-175 (Jan 15, 1996)				
*31	Hebert et al., "FGF5 as a regulator of the hair growth cycle: evidence from targeted and spontaneous mutations" <u>Cell</u> 78(6):1017-1025 (Sep 23, 1994)				
*32	Herr, et al., "Heparin-induced self-association of fibroblast growth factor-2. Evidence for two oligomerization processes" <u>Journal of Biological Chemistry</u> 272(26):16382-16389 (Jun 27, 1997)				
*33	Hillier et al., "Generation and Analysis of 280,000 Human Expressed Sequence Tags" <u>Genome Research</u> 6(9):807-828 (1996)				
*34	Hillier et al., "zr01g05.r1 Stratagene NT2 neuronal precursor 937230 Homo sapiens cDNA clone 650264 5'" (Accession No. AA220994) (Feb 14, 1997)				
*35	Hunter, T., "Cooperation between oncogenes" <u>Cell</u> 64(2):249-270 (Jan 25, 1991)				
*36	Hynes and Stern., "The Biology of erbB-2/neu/HER-2 and Its Role in Cancer." <u>Biochimica et Biophysica Acta</u> 1198(2-3):165-184 (Dec 30, 1994)				
*37	Johnson et al., "Linkage of a gene causing high bone mass to human chromosome 11 (11q12-13)" <u>American Journal of Human Genetics</u> 60(6):1326-1332 (Jun 1997)				
*38	Johnson et al., "The human fibroblast growth factor receptor genes: a common structural arrangement underlies the mechanisms for generating receptor forms that differ in their third immunoglobulin domain" <u>Molecular & Cellular Biology</u> 11(9):4627-4634 (Sep 1991)				
Examiner				Date Considered	
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				Applicant Goddard, A. et al.	
				Filing Date 17 Nov 2003	
				Group 1646	
OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)					
*39	Johnston et al., "bFGF and aFGF induce membrane ruffling in breast cancer cells but not in normal breast epithelial cells: FGFR-4 involvement" <u>Biochemical Journal</u> 306(Pt 2):609-616 (Mar 1, 1995)				
*40	Kiefer et al., "The molecular biology of heparan sulfate fibroblast growth factor receptors" <u>Annals of the New York Academy of Sciences</u> 638:167-176 (1991)				
*41	Lu and Gillett, "An Optimized Protocol for In Situ Hybridization Using PCR-Generated ³³ P-Labeled Riboprobes." <u>Cell Vision</u> 1(2):169-176 (1994)				
*42	Mach et al., "Nature of the interaction of heparin with acidic fibroblast growth factor" <u>Biochemistry</u> 32(20):5480-5489 (May 25, 1993)				
*43	Mathieu et al., "Receptor binding and mitogenic properties of mouse fibroblast growth factor 3. Modulation of response by heparin" <u>Journal of Biological Chemistry</u> 270(41):24197-24203 (Oct 13, 1995)				
*44	McLeskey et al., "MDA-MB-134 breast carcinoma cells overexpress fibroblast growth factor (FGF) receptors and are growth-inhibited by FGF ligands" <u>Cancer Research</u> 54(2):523-530 (Jan 15, 1994)				
*45	McWhirter et al., "A novel fibroblast growth factor gene expressed in the developing nervous system is a downstream target of the chimeric homeodomain oncoprotein E2A-Pbx1" <u>Development</u> 124(17):3221-3232 (Sep 1997)				
*46	Moscatelli, D., "High and low affinity binding sites for basic fibroblast growth factor on cultured cells: absence of a role for low affinity binding in the stimulation of plasminogen activator production by bovine capillary endothelial cells" <u>Journal of Cellular Physiology</u> 131(1):123-130 (Apr 1987)				
*47	Murgue et al., "Identification of a novel variant form of fibroblast growth factor receptor 3 (FGFR3 IIb) in human colonic epithelium" <u>Cancer Research</u> 54(19):5206-5211 (Oct 1, 1994)				
*48	Naski and Ornitz, "FGF signaling in skeletal development" <u>Frontiers in Bioscience</u> 3:D781-794 (Aug 1, 1998)				
*49	Nishimura et al., "Structure and expression of a novel human FGF, FGF-19, expressed in the fetal brain" <u>Biochimica et Biophysica Acta</u> 1444(1):148-151 (Jan 18, 1999)				
*50	Ornitz and Leder, "Ligand specificity and heparin dependence of fibroblast growth factor receptors 1 and 3" <u>Journal of Biological Chemistry</u> 267(23):16305-16311 (Aug 15, 1992)				
*51	Ornitz et al., "Heparin Is Required for Cell-Free Binding of Basic Fibroblast Growth Factor to a Soluble Receptor and for Mitogenesis in Whole Cells" <u>Molecular & Cellular Biology</u> 12:240-247 (1992)				
*52	Ornitz et al., "Receptor specificity of the fibroblast growth factor family" <u>Journal of Biological Chemistry</u> 271(25):15292-15297 (Jun 21, 1996)				
*53	Partanen et al., "FGFR-4, a novel acidic fibroblast growth factor receptor with a distinct expression pattern" <u>EMBO Journal</u> 10(6):1347-1354 (Jun 1991)				
*54	Penault-Llorca et al., "Expression of FGF and FGF receptor genes in human breast cancer" <u>International Journal of Cancer</u> 61(2):170-176 (Apr 10, 1995)				
*55	Perez-Castro et al., "Genomic organization of the mouse fibroblast growth factor receptor 3 (Fgfr3) gene" <u>Genomics</u> 30(2):157-162 (Nov 20, 1995)				
*56	Ravdin and Chamness, "The c-erbB-2 proto-oncogene as a prognostic and predictive marker in breast cancer: a paradigm for the development of other macromolecular markers--a review" <u>Gene</u> 159(1):19-27 (Jun 14, 1995)				
*57	Ron et al., "Fibroblast growth factor receptor 4 is a high affinity receptor for both acidic and basic fibroblast growth factor but not for keratinocyte growth factor" <u>Journal of Biological Chemistry</u> 268(8):5388-5394 (Mar 15, 1993)				
*58	Saksela et al., "Endothelial Cell-derived Heparan Sulfate Binds Basic Fibroblast Growth Factor and Protects It From Proteolytic Degradation" <u>Journal of Cell Biology</u> 107(2):743-751 (Aug 1988)				
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OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)					
*59	Santos-Ocampo et al., "Expression and biological activity of mouse fibroblast growth factor-9" <u>Journal of Biological Chemistry</u> 271(3):1726-1731 (Jan 19, 1996)				
*60	Schwab and Amler, "Amplification of cellular oncogenes: a predictor of clinical outcome in human cancer" <u>Genes, Chromosomes & Cancer</u> 1(3):181-193 (Jan 1990)				
*61	Shaoul et al., "Fibroblast growth factor receptors display both common and distinct signaling pathways" <u>Oncogene</u> 10(8):1553-1561 (Apr 20, 1995)				
*62	Slamon et al., "Human Breast Cancer: Correlation of Relapse and Survival with Amplification of the HER-2/neu Oncogene" <u>Science</u> 235:177-182 (Jan 9, 1987)				
*63	Slamon et al., "Studies of the HER-2/neu Proto-Oncogene in Human Breast and Ovarian Cancer" <u>Science</u> 244:707-712 (May 12, 1989)				
*64	Slavin, J., "Fibroblast growth factors: at the heart of angiogenesis" <u>Cell Biology International</u> 19(5):431-444 (May 1995)				
*65	Somer et al., "Osteoporosis-pseudoglioma syndrome: clinical, morphological, and biochemical studies" <u>Journal of Medical Genetics</u> 25(8):543-549 (Aug 1988)				
*66	Strausberg, R., "oz28c05.x1 Soares_total_fetus_Nb2HF8_9w Homo sapiens cDNA clone IMAGE:1676648 3' mRNA sequence" (Accession No. AI076490) (Aug 10, 1998)				
*67	Vainikka et al., "Association of a 85-kDa serine kinase with activated fibroblast growth factor receptor-4" <u>Journal of Biological Chemistry</u> 271(3):1270-1273 (Jan 19, 1996)				
*68	Vainikka et al., "Fibroblast growth factor receptor-4 shows novel features in genomic structure, ligand binding and signal transduction" <u>EMBO Journal</u> 11(12):4273-4280 (Dec 1992)				
*69	Vainikka et al., "Signal transduction by fibroblast growth factor receptor-4 (FGFR-4). Comparison with FGFR-1" <u>Journal of Biological Chemistry</u> 269(28):18320-18326 (Jul 15, 1994)				
*70	Wang et al., "Fibroblast growth factor receptors have different signaling and mitogenic potentials" <u>Molecular & Cellular Biology</u> 14(1):181-188 (Jan 1994)				
*71	Webster and Donoghue, "FGFR activation in skeletal disorders: too much of a good thing" <u>Trends in Genetics</u> 13(5):178-182 (May 1997)				
*72	Wilkie, A., "Craniosynostosis: Genes and Mechanisms." <u>Human Molecular Genetics</u> 6(10):1647-1656 (1997)				
Examiner				Date Considered	
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